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EXAMINER

RAMANA, ANURADHA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/815,567
Filing Date: March 23, 2001
Appellant(s): PARKER, FRED T.

Lawrence A. Steward
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed July 8, 2008 appealing from the Office action mailed on February 1, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Patent No.	Inventor(s)	Publication Date
5,792,124	Horrigan et al.	8-1998
6,159,187	Park et al.	12-2000
5,380,304	Parker	1-1995
5,599,325	Ju et al.	2-1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 15-20 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant does not describe what is meant by "uniformly spaced coil turns" or how the uniform spacing is measured.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-13, 15-20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the limitation "uniformly spaced coil turns" and in claim 22, the limitation, "uniformly spaced coil turns" renders the respective claims indefinite since it is unclear how the uniform spacing is measured.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-5, 10-13, 15-20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Park et al. (US 6,159,187).

Regarding claim 1, Horrigan et al. disclose a catheter or sheath having a unitary lubricous liner or inner tube 40; a reinforcement means or wire braid 35 terminating proximal to the distal end of inner tube 40; a first outer tube 15; a second outer tube 20 wherein the second outer tube 20 is made of softer material than the first outer tube 15 (Figure 3; col. 2, lines 60-67; col. 3, lines 1-20; and col. 8, lines 28-34); and a distal tip 45. Further, Horrigan et al. teach the use of wire braid 35 to offer better kink resistance (col. 5, lines 1-3).

Horrigan et al. do not disclose the use of a flat wire coil, a round wire coil or a braided wire coil as a reinforcement means.

Park et al. teach a catheter section or sheath with equivalent forms of stiffening members or reinforcement for kink resistance, i.e., a flat wire coil, a round wire coil and a braided wire coil (col. 2, lines 40-43; col. 13, lines 64-67; col. 14, lines 1-26; and Figs.

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7-9). Further, Park et al. teach the importance of designing the sheath to enable its manipulation through increasingly small blood vessels (col. 1, lines 30-52).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the wire braid 35 of Horrigan et al. with a braided wire coil, a flat wire coil or a round wire coil as disclosed by Park et al. to have facilitated the manufacture of the catheter or sheath with a diameter suitable for application in an environment of increasingly small diameters.

Regarding claim 2, Horrigan et al. disclose that the materials of the outer jacket of the sheath including the inner tube 40, wire braid 35, first outer tube 15 and second outer tube 20 are bonded (col. 5, lines 47-56).

Regarding claim 4, Horrigan et al. further disclose that the inner tube 40; the wire braid 35; the first outer tube 15 and the second outer tube 20 are fused or bonded by heating (col. 5, lines 47-56).

Regarding claim 5, although the Horrigan et al. device does not include a radiopaque marker band, attention is again directed to Park et al., which disclose a radiopaque marker band 120 in the distal region of a catheter or sheath 114 to allow viewing of the position of the distal most portion of the sheath 114 (col. 9, lines 25-33). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radiopaque marker band 120 as taught by Park et al. in the second outer tube 20 of the Horrigan et al. device for viewing the position of the distal tip 45 of the Horrigan et al. device.

Regarding claims 10-13, Horrigan et al. further disclose a second outer tube 20 made of a material having a hardness range of Shore durometer 25D to 40D and a first outer tube 40 having a hardness range of Shore durometer 50D to 60D.

Regarding claim 15, Park et al. teach a wire coil 232 made of one or more ribbons or "flat wire" (Figure 7 and col. 14, lines 15-17).

Regarding claim 16, Park et al. teach a sheath 110 having an arcuate distal tip region 112 (Figure 2 and col. 9, lines 21-24).

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Regarding claim 17, Park et al. teach a sheath 110 having an arcuate distal tip region 112 with a typical length of 2.5 cm to 30 cm (col. 9, line 40).

Regarding claim 18, Park et al. teach a sheath 110 having an arcuate distal tip region 112 that is a quadrant of a circle (Figure 2 and col. 9, lines 21-24).

Regarding claim 19, Horrigan et al. disclose that the wire braid 35 should not extend more than 1/3 the length of the second outer tube 20 to provide optimum flexibility of tip 45 (col. 5, lines 1-9) or approximately 3 mm (col. 5, lines 16-20).

Regarding claim 20, Horrigan et al. disclose a sheath having a unitary lubricous liner or inner tube 40.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. in view of Park et al. as applied to claim 1 above, further in view of Parker (US 5,380,304).

Although Horrigan et al. do not disclose a roughened surface, attention is directed to the Parker reference, which teaches an inner tube 22 having an outer rough surface; a wire coil 23; and an outer tube 12 wherein the outer tube 12 is mechanically connected or bonded to the inner tube 22 and the wire coil by the well-known heat shrinking and formation process (col. 3, lines 67-68 and col. 4, lines 1-3).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the sheath of Horrigan et al. by roughening the outer surface of inner tube 22, as taught by Parker, in order to improve bonding between the outer tube 12, the wire coil 23 and the inner tube 22.

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrigan et al. in view of Park et al., further in view of Ju et al (US 5,599,325).

Regarding claim 6, Horrigan et al. do not disclose a sheath wherein the second outer tube 20 of the sheath contains radiopaque filler.

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Ju et al. teach a sheath 10 wherein the distal end portion of the stem member 34 is a soft tip member 40 made from a polymer and radiopaque filler blend (col. 6, lines 6-14).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a second outer tube 20 in the sheath of Horrigan et al. wherein the second outer tube 20 is made from a blend of polymer and radiopaque filler as taught by Ju et al. in order to allow viewing of the position of the sheath in the human body.

Regarding claim 7, Ju et al. further disclose a sheath 10 with an outer layer containing 0 to 42 percent by weight of radiopaque filler, which is the claimed range of about 20% to 85%.

Regarding claim 8, Ju et al. disclose a sheath 10 with a second outer tube containing 0 to 42 percent by weight of radiopaque filler, which is “about 80%” as claimed.

Regarding claim 9, Ju et al. further disclose a sheath 10 with a first outer tube containing 0 percent by weight of radiopaque filler, which is substantially free of radiopaque filler.

(10) Response to Argument

In response to Appellant's argument with regard to the rejection of claims 1-2, 4-5, 10-13, 15-20, 22 and 23 under 35 U.S.C. 103(a) over Horrigan et al. in view of Park et al. (see brief, pages 5-11), it is noted that inventions of references need not be physically combinable to render obvious an applicant's invention. In re Sneed, 710 F. 2d 1544, 218 USPQ 385, 389 (Fed. Cir. 1983). The test for obviousness is not whether the features of a reference may be bodily incorporated into the structure of another reference but what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413 208 USPQ 871 (CCPA 1981).

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Appellant argues on page 9, lines 14-18, that, "The Horrigan reference neither teaches nor suggests an optimal manner of traversing a tortuous passageway in a manner to avoid kinking. In fact, by his use of a braided reinforcement, Horrigan teaches away from the advantages with regard to kink resistance that may be achieved when a coil reinforcement is used."

Appellant further argues on page 9, lines 30-31 and page 10, lines 1-3, with respect to Park et al., "According to the patent, even though the use of a braid reinforcement may improve the ability of the catheter to transmit torque, at times braiding alone is insufficient...col. 9, lines 14-17."

Contrary to Appellant's arguments, Park et al. teach the equivalence of different types of reinforcement such as woven braids, nonwoven braids, coils of ribbon, wire etc. by demonstrating their use in their invention (col. 12, lines 29-38 and col. 14, lines 13-30). The Examiner used Park et al. to establish that it would have been obvious for a person of ordinary skill in the art to have used reinforcement in the form of a flat wire coil instead of a braided round wire coil, as taught by Horrigan, because Park et al. teach the use of a braided wire coil or a flat wire coil as equivalent types of reinforcement utilized in the field of intravascular devices for kinking resistance.

On page 10, lines 29-31, Appellant argues that, "However, in each case, the proper comparison must be to the specific type of reinforcement (such as a braid) with, and without, the formable capabilities of the distal tip."

The Examiner notes that this argument is not pertinent to the claimed features of Appellant's claimed invention.

On page 11, lines 5-9, Appellant further argues, "There is no teaching or suggestion of equivalence or interchangeability in general between such reinforcements, nor is the patent even concerned with making such a comparison. It is clear that Park does not discuss any benefits in kink resistance that may be achieved when a coil reinforcement is utilized instead of a braid, or vice versa."

On page 11, lines 13-16, Appellant then states "Although Park indicates that his device exhibits (among numerous other cited properties) a certain amount of kink

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resistance in some circumstances (col. 2, lines 40-44), this teaching must be read in the context of the invention that he espouses, namely a catheter having a self-formable tip.”

The Examiner emphasizes, Park et al. disclose their “construction technique has the benefit of producing catheter sections having small diameters but with exceptional strength, resistance to kinking, and recovery from kinking (even in vivo) should kinking occur (col. 2, lines 40-43).”

It is the Examiner's position that Park et al. teach the equivalence of a braid or a coil or a combination of one or more of each for reinforcement of an intravascular device for use in an environment of increasingly small diameters (col. 1, lines 9-11 and lines 29-52 and col. 8, lines 29-36). Specifically, Park et al. teach the use of a single interior coil (232, Fig. 7, col. 14, lines 12-23), or one or more ribbon coils (236, Fig. 8, col. 14, lines 24-26), or a woven braid (242, Fig. 9, col. 14, lines 27-30). Park et al. teach the use of a woven braid (206, Fig. 3) made up of a suitable number of ribbons woven in a radial in-and-out fashion (col. 11, lines 61-67 and col. 12, lines 29-44). Park et al. also teach the use of a braid (222, Fig. 5) that includes a number of coils which are not woven in an in-and-out fashion (col. 13, lines 65-67).

Thus, Park et al. clearly teach a woven or non-woven braid with one or more coils wherein the coil is a wire having a round cross section or is a ribbon having a “rectangular, oval or semi-oval cross section (col. 12, lines 39-44), for the purpose of reinforcing intravascular devices with small overall diameters for exceptional kink resistance.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the wire braid 35 of Horrigan et al. with a braided wire coil, a flat wire coil or a round wire coil as disclosed by Park et al. to have facilitated the manufacture of the catheter or sheath with a diameter suitable for application in an environment of increasingly small diameters with exceptional kink resistance.

Thus, it is the Examiner's position that the combination of Horrigan et al. and Park et al. renders Appellant's claimed invention obvious.

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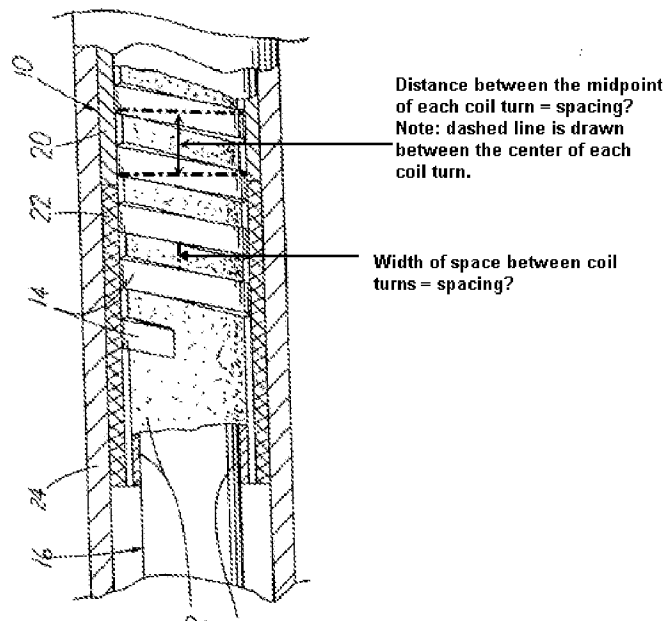
In response to Appellant's arguments with respect to the rejections of claims 1-13, 15-20 and 22 under 35 USC 112 first paragraph, the Examiner notes that the introduction of the limitation, "comprising a plurality of uniformly spaced coil turns" raises the issue of new matter and lack of written description.

Although "one skilled in the art would absolutely have no difficulty understanding the meaning of this terminology in the present claims" as contended by the Appellant, Appellant's original disclosure does not provide support for the claimed invention. As clearly stated in the MPEP, "the first paragraph of 35 U.S.C. 112 requires that the specification shall contain a written description of the invention ****" (MPEP 2163 (I)). The Examiner emphasizes that US Patent No. 5,380,304 has not been incorporated by reference in the specification of the instant application. Therefore, any similarity between Figures 2-4 of the instant application and US Patent No. 5,380,304, does not eliminate the requirement for compliance with 35 USC 112 first paragraph.

Consequently, the rejections of claims 1-13, 15-20 and 22 under 35 USC 112 second paragraph are deemed proper.

Regarding the rejections of claims 1-13, 15-20 and 22 under 35 USC 112 second paragraph, the Examiner maintains that it isn't clear how the spacing between the coil turns is measured. For e.g., is the "spacing" the width of the space between the coils or the distance between the midpoints of the coils as illustrated on the following page.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections are proper and should be sustained.

Respectfully submitted,

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